

REMARKS

This Amendment is being filed before examination of this application. Claims 13 and 15 have been amended, claims 9, 14, and 16 have been canceled and claims 17 and 18 have been added. Accordingly, claims 10-11 and 13, 15, 17 and 18 are pending in the application. Reconsideration of this application is respectfully requested.

Claim 14 was rejected under 35 U.S.C. §112, second paragraph. Applicants respectfully traverse this rejection.

According to the rejection, claim 14 is indefinite because of the use of the expression "other polysaccharide fibers". Although claim 14 has been canceled, the expression does appear in amended claim 13. (It does not appear in new claim 18 which is otherwise identical to claim 13.) Applicants believe that amended claim 13 makes it abundantly clear that the expression refers to highly absorbent fibers that can absorb at least 25 g/g of deionized water and are polysaccharide fibers not already listed in the claim.

Since this meaning is abundantly clear, Applicants submit that the rejection should be withdrawn.

Next, claims 9-11 and 13-16 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,842,996 (hereafter "Carlisle") in view of U.S. Patent No. 5,899,893 (hereafter "Dyer, et al.") and further in view of U.S. Patent No. 5,124,197 (hereafter "Bernardin, et al."). Applicants respectfully traverse this rejection.

The present invention is concerned with a method of treating an acute wound using a wound dressing (as a substitute for a biological dressing or skin graft) wherein the wound dressing comprises highly absorbent fibers.

Applicants have found that by the use of absorbent fibers in the above method, fibrous dressings can be used as substitutes for biological dressings. Biological dressings are sophisticated and, therefore, tend to be expensive and carry the same risks of cross-contamination that are encountered with blood and blood products. The advantages of the new method embodied in Applicants' claims include that the dressings can be used as a substitute for a biological dressing at lower cost and without the risk of contamination.

Carlisle, on the other hand, is concerned with pressure dressings. According to Carlisle, pressure dressings are fundamental in the preparation of wounds for skin grafting (column 6, lines 36 to 37). Carlisle does not, therefore, consider his dressing as a substitute for a biological dressing, but rather as a preparation for it. Carlisle would not, therefore, motivate the person of ordinary skill in the art to use a fibrous dressing as a substitute for a biological dressing.

Importantly, in the Response to Arguments referring to Carlisle, it is commented that the Carlisle wound dressings "are formed of the same materials" as that of Applicants' dressings and, therefore, the particular use fails to impart a patentable distinction. However, Carlisle, at column 5, lines 19 to 26, describes the material for his construction as "short fiber hard wood pulp from the Kraft process, mixed with longer fiber soft wood pulp produced by the neutral sulphite process". Wood pulp is cellulose. This is not the same material as is used in Applicants' dressings. Wood pulp is not highly absorbent modified cellulose as recited in Applicants' claims, nor is it highly absorbent fibers that can absorb at least 25g/g of deionized water as recited in Applicants' claims.

The fact that the materials are different is illustrated by the different behavior of the materials. Carlisle's dressing is said to prevent healing tissues from becoming entangled with the dressing material (col. 3, last sentence). Applicants' dressings allow outgrowth of the wound epithelium during treatment as recited in Applicants' independent claims. The material differences, and the differences in behavior, call into question the basis for the rejection of the claims based on Carlisle. Applicants' materials and their method of use do make a patentable distinction over the art.

Nevertheless, in order to advance the prosecution of this application, Applicants have deleted "cellulose" from the claims.

Further, dressings of Carlisle are dense, laminar dressings that wick laterally and bar the movement of exudate into the dressing (column 3, lines 17-20). In use, the dressings of Carlisle are placed on the wound and, at dressing change time, the dressings are removed by delaminating or soaking or providing the dressings with a wound contact layer that has the property of release from the wound. Dressing changes occur every 12 hours or so. Carlisle does not, therefore, suggest that the dressings can

be used in the manner of a biological dressing and, as claimed herein, which is left in place in its entirety and undisturbed until the wound has healed. The differences between the method and dressing characteristics of Carlisle compared to Applicants' invention are shown particularly in the wording of Claim 13. Claim 13 has the method steps of: allowing the dressing to become adhered to the wound; leaving the dressing in place until it dries out to form a crust; and removing the dressing once the wound has healed. Applicants note that the claims are method claims. Carlisle does not disclose the claimed method steps and does not suggest them. Carlisle also does not teach that the dressing is left in place, or vertical wicking into the dressing, both as required by Applicants' claims. In contrast, Carlisle discloses changing of the dressing, and only lateral wicking, and Carlisle does not suggest that there would be any advantage in vertical wicking into the dressing.

Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds as claimed, the dressing adheres to the wound. (See page 5, second paragraph). This type of behavior would usually only be seen with a biological dressing such as allograft, and it is a truly surprising discovery by the Applicants. It is illustrated particularly in Example 1, where it is described that the wound dressing dried out to form a crust as wound healing was in progress, and the dressing remained in place for 14 days. This method of use is very different from that contemplated in Carlisle where the emphasis is on the dressing being changed.

In the rejection, Applicants' arguments concerning the method of use of the dressing were not found to be persuasive in terms of the time frame for which the dressing is left in place on the wound. Applicants disagree. The claims require that the dressing is left in place "until the dressing dries out to form a crust". Clearly this would take longer, or shorter, depending on the wound, but it is not at all contemplated by Carlisle. Even if the dressing of Carlisle is left in place, the suggestion is to remove it **before** the dressing dries out. Further, certain of the claims also require that the dressing be left in place for epithelial outgrowth and vertical wicking into the dressing to occur. According to the rejection, this limitation fails to set forth any specific time or duration parameters. Again Applicants disagree. Certainly, depending on many

factors, the amount of wound exudate and time to healing of a wound will vary. The claim language accounts for this variation.

Applicants' claim 13, part c, requires that the dressing be left in place for epithelial outgrowth and vertical wicking into the dressing to occur and until the dressing dries out to form a crust. Part d then requires that the dressing be removed once the wound is healed. As mentioned above, Carlisle's dressing prevents outgrowth and mentions at the end of column 3 that the highly dense construction of the material disperses exudate to a low interlayer adhesion level. Carlisle's dressing cannot, therefore, be left in place for vertical wicking to occur as Carlisle's dressing does not permit vertical wicking. The requirement for epithelial outgrowth and vertical wicking provide further distinction over the art which appears to be overlooked in the rejection.

It does appear to be accepted in this rejection and in previous rejections that Carlisle does not teach vertical wicking (current Action, bottom of page 10), and finally in this Action that the wicking in Bernardin, et al. is not the vertical wicking described by Applicants. Nevertheless, it is argued in the rejection that this does not establish any patentable distinction over the cited art which, according to the rejection, provide for the same components as claimed. However, as explained above, the same components are not disclosed by the cited art.

At the middle of page 12 of this Action, even though the Action(s) earlier accepted that the art does not teach vertical wicking, the confusion over vertical wicking is repeated. It is argued in the rejection that the prior art in combination recognizes wound dressings /absorbent articles for the treatment of wounds whereby the dressings possess improved vertical wicking properties. However, again, the vertical wicking described by the art is with reference to a vertically held strip of test material. In relation to the wound this wicking is **lateral** not vertical. Applicants' reference to vertical wicking is with respect to the wound, that is, vertically out of the wound and into the dressing. The art does not describe the wicking of exudate vertically out of the wound and into the dressing. As explained above, Carlisle is at pains to describe that his dressing does not have the property of vertical wicking in Applicants' terms. This property alone provides a patentable distinction over the prior art.

Still, the rejection relies on Bernardin, et al. for teaching absorbent webs of fibers with vertical wicking. However, again, it is clear from Bernardin, et al. that the expression "vertical wicking" is being used in the same manner as it is used in Dyer, et al. As discussed above, "vertical wicking" is being used in Bernardin, et al. as the wicking of a vertically held strip of a test material against gravity. In relation to the wound, this wicking would be lateral, not into the dressing. See column 8, lines 1-22, of Bernardin, et al. Thus, Bernardin, et al. does not teach vertical wicking into the dressing in the same sense as it is used in Applicants' claims. (Similarly, the wicking in Dyer, et al. is the wicking of a vertically held strip of a test material against gravity. See column 4, lines 9 to 11, column 7, lines 41 to 43 and column 24, line 63, through column 26, line 2 of Dyer, et al.). There is no disclosure of vertical wicking into the dressing in Bernardin, et al. (or in Dyer, et al.), nor is there a disclosure that the property of vertical wicking into the dressing could be of an advantage when used to treat acute wounds.

The rejection also relies on Dyer, et al. to supply the deficiencies of Carlisle regarding the amount of water absorbed by the dressings. However, there is no suggestion in Carlisle to do so. While it is argued at page 5 of the Action that there is motivation to combine Dyer, et al. and Carlisle to obtain a wound dressing that imparts vertical wicking, Applicants see no motivation for at least two reasons. First, Carlisle is concerned with pressure dressings. The dressings have a deep lamellar structure to give a highly dense dressing that is able to transmit pressure to the wound. For this reason, Carlisle selects its dressing materials carefully and specifically recites in claim 1 that the dressing should have limited compressibility. The limited compressibility means that the tape used to adhere the dressing to the wound can increase pressure application to the wound (column 1, lines 59-65). The dressing material of Dyer, et al., is a foam. It is well known that foams are highly compressible. A person having ordinary skill in the art would not, therefore, substitute the foam of Dyer, et al. for the lamellar dressing of Carlisle in order to improve the Carlisle dressing as the combination would mean that the Carlisle dressing no longer functioned as a pressure dressing. Second, neither Dyer, et al., nor Carlisle discloses vertical wicking into the dressing or that the property would have an advantage when used in a dressing on an acute wound.

It is also implied on page 5 of the Action that the amount of water absorbed by the dressings in Applicants' claims is nothing more than a difference in concentration. This treats Applicants' claims as though they relate to a composition with different optimum ranges from a known composition. Clearly, that is not the case.

According to the rejection, Applicants have not demonstrated any unexpected or superior results through the use of their wound dressing method steps over that of the prior art. Applicants again disagree. Applicants' dressing and method are highly unusual in that, when used in the treatment of acute wounds, the dressing adheres to the wound and forms a crust. This type of behavior would usually be seen only with a biological dressing such as allograft, and it is a truly surprising discovery. Specifically, page 3 of the specification reads as follows:

We have found that a wound dressing, to be suitable as a substitute for a biological dressing preferably is adherent to the wound without preventing the outgrowth of the epithelium. This is truly surprising since conventional wisdom teaches that wound dressings should not adhere to the acute wound and many known dressings are provided with measures to avoid adherence such as being impregnated with paraffin or being coated with silicone. We have found that an adherent dressing has advantages over the prior art dressings which allow the dressing to be used in those situations where a biological dressing would otherwise be used.

We have also found that wound dressings suitable as replacements for biological dressings preferably promote the migration of enzymes, neutrophils, fibroblasts and cellular debris into the dressing. Whilst not wishing to be bound by theory we believe that this migration, which we term as "vertical wicking", modulates the inflammatory response of the wound and contributes to successful healing of the wound.

That the dressing adheres to the wound and acts like a biological dressing when it is not one is an unexpected result. Applicants believe that this is due to the modulation of the inflammatory response caused by the vertical wicking property of the dressing. The assertion in the rejection is therefore clearly incorrect.

The unexpected results of vertical wicking into the dressing are also shown in the Examples where, in Example 1, dressings used in the method of the invention adhere to the wound in the same manner as allograft skin. Applicants' claims recite that, in the method, the dressing becomes adhered to the wound which again is a feature of biological dressings and is a property that is avoided by known wound dressings. In Example 2, the adherent properties of dressings according to the invention are described again and the evidence of vertical wicking into the dressing is given. In Example 3, the method of the invention is used to provide a temporary cover to excised skin. The description points to several unexpected results which are attributed to vertical wicking into the dressing. Accordingly, the rejection is therefore incorrect that that there are no unexpected results

It was also argued in a previous rejection that although the dressing of Carlisle must be saturated or provided with a wound contact layer to be removed, this does not impart patentability to the claims. However, Applicants made mention of this difference in method because Carlisle obviously removes the dressing before healing is complete unlike Applicants' method. Contrast Carlisle's saturating and wound contact layer and the method steps these imply with steps c) and d) of claim 13.

The inventors of the present invention discovered that it is possible to treat burns by the use of a fibrous dressing that is able to wick vertically into the dressing and becomes adhered to the wound. This behavior is truly surprising. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. mention vertical wicking into the dressing as it is used herein, or that vertical wicking into the dressing could be an advantage in a dressing used to treat acute wounds. Neither Carlisle, nor Dyer, et al., nor Bernardin, et al. disclose the method of treating an acute wound with a dressing that vertically wicks into the dressing or that is left in place as has been claimed by Applicants. No combination of the teachings of Carlisle, Dyer, et al., and Bernardin, et al. suggest the claimed

methods. For these reasons, Applicants believe that the claims are patentable over the cited documents.

For all these reasons, withdrawal of the rejections, favorable reconsideration of this application, and allowance of the pending claims, are all earnestly solicited.

Respectfully submitted,

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